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MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632			EXAMINER TYSON, MELANIE RUANO	
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The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GARY KARLIN MICHELSON

Appeal 2009-008690
Application 10/098,683
Technology Center 3700

Before STEVEN D.A. MCCARTHY, MICHAEL W. O'NEILL, and
FRED A. SILVERBERG, *Administrative Patent Judges*.

SILVERBERG, *Administrative Patent Judge*.

DECISION ON APPEAL¹

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

Gary Karlin Michelson (Appellant) seeks our review under 35 U.S.C. § 134 of the final rejection of claims 54-65, 67-90 and 92-108. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

THE INVENTION

Appellant's claimed invention is directed to a surgically implantable device for the stabilization of adjacent vertebrae of the human spine (Spec. 2: 3-7).

Claim 54, reproduced below, is representative of the subject matter on appeal.

54. An apparatus comprising:
an interbody spinal fusion implant for surgical implantation within a disc space between two adjacent vertebral bodies in a segment of a human spine, said implant comprising upper and lower portions for contacting each of the adjacent vertebral bodies when positioned therein, each of said upper and lower portions having at least one opening adapted to communicate with one of the adjacent vertebral bodies, said openings of said upper and lower portions being in communication with one another and adapted for permitting for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant, said implant including a hollow interior for holding bone growth promoting material, said hollow interior being in communication with at least one opening in each of said upper and lower portions, said implant having an insertion end for entry into the spine and a trailing end, said trailing end having a rear wall between said upper and lower portions;

a liquid fusion promoting material in at least a portion of said hollow interior to promote bone growth from adjacent

vertebral body to adjacent vertebral body through said implant;
and

a solid fusion promoting material other than bone, said
solid fusion promoting material being in at least a portion of
said hollow interior to promote bone growth from adjacent
vertebral body to adjacent vertebral body through said implant.

THE REJECTIONS

The following rejections by the Examiner are before us for review:

1. Claims 54-65, 67-78 and 104-106 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.
2. Claims 54-65, 67-90 and 92-108 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ray (US 5,026,373, issued Jun. 25, 1991).

ISSUES²

The issues before us are: (1) whether the Examiner erred in finding that the invention called for in independent claim 54 does not comply with the written description requirement of 35 U.S.C. § 112, first paragraph (Reply Br. 2, App. Br. 4); and (2) whether the Examiner failed to articulate an adequate reason with rational underpinning why it would have been obvious to employ more than one material to promote bone growth, as called for in independent claims 54 and 79 (Reply, Br. 4, App. Br. 9).

² Appellant seeks review of the Examiner's objection to the amendment filed Jun 18, 2007 (App. Br. 7). However, such issues are not within the jurisdiction of the Board. *See In re Mindick*, 371 F.2d 892, 894 (CCPA 1967), and, therefore, can not be treated in this appeal. *See also* MPEP §§ 608.04(c) and 2163.06 II (8th ed., Rev. 8, Jul. 2010)

ANALYSIS

Rejection under 35 U.S.C. § 112

The Examiner found that claim 54 does not comply with the written description requirement of 35 U.S.C. § 112, first paragraph, since “Appellant failed to disclose a liquid fusion promoting material and a solid fusion promoting material at the time the application was filed (see claims 54, 67, and 104-106)” (Ans. 3). The Examiner found that “Appellant simply disclosed bone fusion promoting material, such as hydroxyapatite, tricalcium phosphate, and bone morphogenetic protein” (*id*).

Appellant contends that “the solid states of hydroxyapatite and hydroxyapatite tricalcium phosphate, and the liquid state of bone morphogenetic protein (BMP) are inherent properties of those materials, when used to promote bone fusion” (App. Br. 5).

The Examiner found that “[a]lthough the materials disclosed by the appellant may inherently contain these properties, the appellant did not disclose all liquid and solid fusion promoting materials” (Ans. 5).

Appellant contends that one “is not required to disclose all liquid and solid fusion promoting materials to support the recitations of [the] claims” (App. Br 5). Appellant contends that “one of ordinary skill . . . would have understood that Appellant disclosed solid and liquid fusion promoting materials, and would conclude that Appellant was in possession of the invention as claimed” (*id*).

“[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en

banc). “[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” *Id.* “Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.” *Id.* “This inquiry . . . is a question of fact.” *Id.* Further, the Examiner bears an initial burden of setting forth a reasonable explanation as to why the Examiner believes that the claimed invention does not comply with the written description requirement of 35 U.S.C. § 112, first paragraph. Once Appellant responds, in order to maintain the rejection, the Examiner must specifically explain why Appellant’s response is insufficient. *In re Alton*, 76 F.3d 1168, 1175-1176 (Fed. Cir. 1996) (“Once the examiner or Board carries the burden of making out a prima facie case of unpatentability, ‘the burden of coming forward with evidence or argument shifts to the applicant.’ . . . ‘After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of the evidence with due consideration to persuasiveness of argument[.]’” including any and all rebuttals of the evidence of argument submitted by applicant.)

Once Appellant made the contention and provided evidence in the form of scholarly articles (*see* Evidence Appendix) that the solid states of hydroxyapatite and hydroxyapatite tricalcium phosphate, and the liquid state of bone morphogenetic protein (BMP) are inherent properties, the Examiner must have specifically explained why Appellant’s response is insufficient. *Id.* at 1175-1176.

However, the Examiner has not disputed Appellant’s contention and evidence in the form of scholarly articles that the solid states of

hydroxyapatite and hydroxyapatite tricalcium phosphate and the liquid state of bone morphogenetic protein (BMP) are inherent properties (*see* App. Br. 6).

Thus, we find that the Examiner has not sufficiently responded to Appellant and are constrained not to sustain the rejection.

We reverse the rejection of claim 54, and of dependent claims 55-65, 67-78 and 104-106.

Rejection under 35 U.S.C. § 103(a)

Appellant contends that Ray only describes use of bone chips or other bone-inducing substance (App. Br. 9). Appellant contends that “[a]though the bone chips or cancellous bone of Ray are solid and bioresorbable materials, the bone chips or cancellous bone are not liquid or bioactive materials” (Reply Br. 4, *see also* App. Br. 9). Therefore, Appellant contends that Ray does not describe a spinal fusion implant combined with (1) a liquid and a solid fusion promoting material, as called for in independent claim 54, or (2) a bioactive and a bioresorbable material, as called for in independent claim 79 (App. Br. 9).

The Examiner found that (1) Ray describes a spinal fusion implant having a hollow interior for holding bone graft or bone growth promoting material, as called for in independent claims 54 and 79, and (2) that Ray does not describe the claimed bone growth promoting materials (Ans. 3). The Examiner found that “the bone growth promoting materials claimed are well known in the art” (Ans. 3-4).

The Examiner concluded that “[i]t is well within the general knowledge of one having ordinary skill in the art to combine well known

bone growth promoting materials in order to effectively promote bone growth and enhance fixation” (Ans. 5).

The Examiner concluded that

It would have been an obvious matter of design choice to employ more than one bone growth promoting material in the Ray implant, such as the combination of a liquid and solid fusion promoting material as claimed, since [A]ppellant has not disclosed that having two different growth promoting materials would solve a stated problem or is used for any particular purpose, and it appears that the implant would perform equally well with one solid fusion promoting material as disclosed by Ray.

(Ans. 5-6).

Claim 54 calls for, *inter alia*, a spinal fusion implant including a hollow interior, with a liquid fusion promoting material and a solid fusion promoting material other than bone being in at least a portion of said hollow interior.

Claim 79 calls for, *inter alia*, a spinal fusion implant including a hollow interior, with a bioactive material and a bioresorbable material being in at least a portion of said hollow interior.

Ray describes a fusion cage 10, 50 (col. 7, l. 14; col. 8, l. 27), wherein “the cage is packed with bone chips or other bone-inducing substance” (col. 10, ll. 10-11).

Ray is silent as to whether the cage 10, 50 could accommodate a liquid (bioactive) material, or whether it could accommodate both a solid (bioresorbable) material and a liquid (bioactive) material. As such, it becomes incumbent upon the Examiner to provide an adequate basis in fact and/or technical reasoning that would support a finding that Ray’s cage 10, 50 could accommodate a solid (bioresorbable) material and a liquid

(bioactive) material. The Examiner opined, *inter alia*, that it would have been an obvious matter of design choice to employ more than one bone growth material in the Ray implant, wherein the bone growth materials would be a solid and a liquid (Ans. 5-6). We find that such a statement is a conclusory statement not supported by Ray's actual disclosure, and is thus based upon speculation. We conclude that such a rationale does not provide an adequate basis in fact and/or technical reasoning since it is unclear whether Ray's cage 10, 50 could accommodate a liquid, or whether it could accommodate both a solid and a liquid. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.") *In re Warner*, 379 F.2d 1011, 1017 (CCPA 1967) ("The legal conclusion of obviousness must be supported by facts. Where the legal conclusion is not supported by facts it cannot stand.")

We reverse the rejection of claims 54-65, 67-90 and 92-108 over Ray.

CONCLUSIONS

The Examiner has erred in finding that the invention called for in independent claim 54 does not comply with the written description requirement of 35 U.S.C. § 112, first paragraph.

The Examiner failed to articulate an adequate reason with rational underpinning why it would have been obvious to employ more than one material to promote bone growth, as called for in independent claims 54 and 79.

DECISION

The decision of the Examiner to reject claims 54-65, 67-90 and 92-108 is reversed.

REVERSED

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